IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NATERA, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
GENOSITY INC.,	)	**JURY TRIAL DEMANDED**
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Natera, Inc. ("Natera"), for its Complaint against defendant Genosity Inc. ("Genosity"), hereby alleges as follows:

OVERVIEW OF THE ACTION

1. This is a patent infringement action brought under 35 U.S.C. § 271 arising from Genosity's infringement of Natera's United States Patent No. 10,732,220 (the "'220 Patent") (Ex. 1) by the manufacture, use, sale, and offer to sell of Genosity's AsTra testing system, AsTra Profile, AsTra One, AsTra Next, Myeloid NGS Molecular Profile and any other products that use the same technology as the previously mentioned products (collectively, the "Accused Products"). The Accused Products use ArcherDX, Inc.'s ("Archer's") ctDNA chemistry and region-specific primers, which infringe the '220 Patent. Genosity does not have freedom to operate its AsTra products for minimal residual disease ("MRD") and personalized cancer monitoring. Natera brings this action to stop Genosity's infringement of Natera's innovative and patented technology.

THE PARTIES

2. Plaintiff Natera is a corporation organized and existing under the laws of Delaware, with its principal place of business at 201 Industrial Road, San Carlos, California 94070.

3. Founded in 2004, Natera (f.k.a. Gene Security Network) is a pioneering molecular technology company with industry-leading healthcare diagnostics products. Natera is dedicated to improving disease management for oncology, reproductive health, and organ transplantation. For well over a decade, Natera has been researching and developing non-invasive methods for analyzing DNA to help patients and doctors manage diseases. These ongoing efforts have given rise to novel and proprietary genetic testing services to assist with life- saving health management.

4. Since 2009, Natera has launched ten molecular tests, many of which are available through major health plans accounting for more than 140 million covered persons in the United States. Natera's own robust laboratory processes thousands of genetic tests per month.

5. Natera's pioneering and ongoing innovation is especially evident in the field of cell-free DNA ("cfDNA") based testing. Natera has developed unique and highly optimized cfDNA-based processes that can be used to test non-invasively for a range of conditions. Natera developed a best-in-class cfDNA test, Panorama, which showcases Natera's mastery of cfDNA in the field of non-invasive diagnostics. Panorama is considered the industry-leading test in this space, with over two million tests performed commercially and more than twenty-six peer-reviewed publications. Natera has also applied its cfDNA platform to the challenge of detecting and monitoring cancer.

6. In detecting and monitoring cancer, the use of minimally invasive, blood-based tests offers significant advantages over older more invasive methods, such as the tumor biopsy. But a significant technological challenge is that blood-based testing requires the measurement of exceedingly small amounts of relevant genetic material—circulating-tumor DNA ("ctDNA")—within a much larger blood sample. Natera's approach combines proprietary molecular biology

and computational techniques to measure genomic variations in tiny amounts of DNA, representing a fundamental advance in molecular biology.

7. Natera has researched and developed cfDNA technology to provide patients and healthcare providers with tools for early clinically meaningful detection and monitoring of cancer.

8. Natera's cfDNA platform is the result of over a decade of arduous work and investment of, on average, more than 50 million dollars per year in research and development. Natera has expended substantial resources researching and developing its technologies and establishing its reputation among physicians, insurers, and regulators as a company committed to sound science and consistently accurate, reliable results. This research, and the technological innovations resulting therefrom, are protected by a substantial patent portfolio, with over 200 patents issued or pending worldwide, including greater than 60 in the field of oncology.

9. Among these patented inventions is the '220 patent, which Genosity infringes. Genosity has used Natera's patented technology without permission and in violation of the patent laws.

10. On information and belief, defendant Genosity is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 485F US Highway 1 South, Iselin, NJ, 08830.

11. Instead of developing its own science for its cancer detection and monitoring products, Genosity has unlawfully used and is using Natera's patented technology.

JURISDICTION AND VENUE

12. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq*.

13. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) because this is a civil action arising under the Patent Act and declaratory judgment jurisdiction under 28 U.S.C. §§ 2201-2202.

14. This Court has personal jurisdiction over Genosity because Genosity is a Delaware corporation.

15. This Court also has jurisdiction over Genosity because, upon information and belief, Genosity, directly or indirectly, uses, offers for sale, and/or sells the Accused Products throughout the United States, including in this judicial district.

16. Venue is proper in this Court under 28 U.S.C. § 1400(b) because Genosity is a Delaware corporation.

BACKGROUND

17. Since 2004, Natera has been a global leader in genetic testing, diagnostics, and DNA testing, including cfDNA testing. Natera's mission is to improve the management of disease worldwide and focuses on reproductive health, oncology, and organ transplantation. In pursuit of these goals, Natera has developed novel technologies to make significant and accurate clinical assessments from the miniscule amounts of cfDNA present in a single blood sample. These technologies include methods to manipulate cfDNA in unconventional ways to capture information about genetic variations in cfDNA and usefully transform that information for noninvasive testing.

18. Natera develops and commercializes innovative, non-traditional methods for manipulating and analyzing cfDNA, and offers a host of proprietary cfDNA genetic testing services to the public to assist patients and doctors to evaluate and track critical health concerns.

19. Since its founding, Natera has researched, developed, and released ten molecular tests with applications in prenatal diagnostics, cancer, and organ transplants, many of which are available through major health plans, or covered by Medicare or Medicaid, and therefore available to most patients in need of those tests. Natera's tests have helped more than two million people to date. Natera's robust laboratory now processes tens of thousands of tests per month in the United States and internationally, improving the ability of physicians to monitor and manage crucial health issues and patients to prosper around the world.

20. Building on these innovations, in 2017, Natera launched its cfDNA diagnostic test to detect and monitor cancer, called Signatera®. Signatera® is a personalized ctDNA surveillance tool that detects MRD when assessing disease recurrence or treatment response in solid tumors. Signatera® is designed to screen for multiple tumor-derived targets with each assay. It is optimized to detect extremely low quantities of ctDNA and provides early knowledge of disease recurrence with a >99.5% clinical test specificity.

21. MRD assessment has become a standard of care in the management of patients with hematological malignancies, but until recently it has not been possible in solid cancers due to technical limitations. Accurate MRD testing and molecular monitoring offers the potential for physicians to change or escalate treatment in patients who are MRD-positive, and to de-escalate or avoid unnecessary treatment in patients who are MRD-negative. It also holds potential as a surrogate endpoint in clinical trials.

22. Natera's technology has been validated in multiple clinical studies. In Cancer Research UK/University College London's Tracking Cancer Evolution through Therapy ("TRACERx"), Natera's technology was used for the multi-year monitoring of patient-specific single-nucleotide variants (SNVs) in plasma, to understand the evolution of cancer mutations over

time, and to monitor patients for disease recurrence. Results from the first 100 early-stage lung cancer patients analyzed as part of the study were featured on the cover of the May 2017 issue of Nature and showed that an early prototype version of Signatera® identified 43% more ctDNA-positive early-stage lung cancer cases than a generic lung cancer panel and demonstrated its potential to detect residual disease, measure treatment response, and identify recurrence up to 11 months earlier than the standard of care, with a sensitivity of 93% at time of relapse.

23. Natera has also collaborated with Aarhus University; Imperial College London; the University of Leicester; Institut Jules Bordet; the Fox Chase Cancer Center; the University of California, San Francisco; and Foundation Medicine, Inc. with respect to cancer research.

24. The U.S. Food and Drug Administration ("FDA") recognized the importance of Natera's Signatera® and granted it "Breakthrough Device" designation on May 6, 2019. That designation will help accelerate FDA assessment and review of Signatera as an in vitro diagnostic for use in pharmaceutical trials.

25. Signatera®'s validation has also led Medicare to issue a draft Local Coverage Determination ("LCD") for Signatera® in March 2019. In its draft LCD, Medicare determined that "[t]he analytical validity and clinical validity of minimal residual disease testing using cell-free DNA, and Signatera® in particular, appears to be well established based on available information for the test." In August 2019, the Palmetto MolDX program, which is run by Medicare Administrative Contractors, proposed an LCD for use of the "Signatera® molecular residual disease (MRD) test in patients with certain forms of colorectal cancer."

26. The '220 patent resulted from Natera's years-long research in developing innovative new methods for amplifying and sequencing nucleic acids, including cell-free DNA.

General Background of the Invention

27. The ’220 patent, attached hereto as Exhibit 1, is entitled “Methods for Simultaneous Amplification of Target Loci” and was issued by the United States Patent and Trademark Office (“USPTO”) on August 4, 2020.

28. Natera is the owner of all rights, title, and interest to the ’220 patent which is valid and enforceable.

29. The ’220 patent issued from Application No. 16/743,724, filed on January 15, 2020. Application No. 16/743,724 is a continuation of Application No. 14/918,544, filed on October 20, 2015.

30. The ’220 patent shares the specification of Application No. 14/918,544, filed on October 20, 2015.

31. The ’220 patent claims methods for simultaneously amplifying multiple nucleic acid regions of interest in a single reaction volume using universal primers, gene specific primers and molecular barcode. The claimed methods recite ligating adaptors to cell-free DNA followed by two polymerase chain reactions (“PCR”) to amplify and high-throughput sequencing (“HTS”) to sequence the newly created nucleic acids. Independent claim 1 of the ’220 patent recites:

> A method for amplifying and sequencing DNA, comprising:
>
> ligating adaptors to cell-free DNA isolated from a biological sample, wherein the adaptors each comprises a universal priming sequence and a molecular barcode;
>
> performing a first PCR to simultaneously amplify at least 10 target loci using a first universal primer and at least 10 target-specific primers in a single reaction volume;
>
> performing a second, nested PCR to simultaneously amplify the at least 10 target loci using a second universal primer and at least 10 inner target-specific primers in a single reaction volume, wherein at least one of the primers comprises a sequencing tag; and

performing high-throughput sequencing to sequence the amplified DNA comprising the target loci.

The '220 Patent Is Not Directed to a Natural Phenomenon and its Steps Were Not Routine or Conventional

32. The claims of the '220 patent recite a patentable and innovative solution to a significant problem in using cell-free DNA that specifically addresses the difficulty in simultaneously amplifying multiple DNA targets and sequencing them. The claims are directed to an improved process for preparing non-natural DNA, and are analogous to claims found patentable in *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, 967 F.3d 1319 (Fed. Cir. 2020).

33. At the time of the invention, skilled artisans were interested in "simultaneous amplification of many target nucleic acids in a sample of interest" (called "multiplex PCR") because such a process could "significantly simplify experimental procedures and shorten the time required for nucleic acid analysis and detection." '220 Patent, 2:63-64, -3:1-3. Such amplification involved the use of synthetic DNA molecules called "primers" that bind to certain DNA regions. But there was a problem doing this:

> **[W]hen multiple pairs [of primers] are added to the same PCR reaction, non-target amplification products may be generated, such as amplified primer dimers**. The risk of generating such products increases as the number of primers increases. These non-target amplicons significantly limit the use of amplified products for further analysis and/or assays.

'220 Patent, 3:4-9 (emphasis added). In essence, the primers bind to and amplify themselves rather than their intended targets. These amplified primer-dimer artifacts then compete with the actual amplified targets at the sequencing stage, resulting in significant problems. '220 Patent, 47:36-44, 86:11-14. One solution, the patent explains, was to split up the reactions into individual PCR reactions with a single primer pair or a smaller number of primer pairs. '220 Patent, 86:18-21. But if there is only a small amount of sample DNA to start with (as is often the case when analyzing cell-free DNA), dividing that limited amount into even smaller reaction vessels is impractical.

'220 Patent, 86:21-25. Thus, Natera's patent explains, "improved methods are needed to reduce the formation of non-target amplicons during multiplex PCR." '220 Patent, 3:9-11.

34. The patent teaches and claims a solution to this problem—a method for ***preparing a non-natural*** DNA and sequencing it. The method includes specific process steps. First, cell-free DNA is altered by ligating a synthetic adaptor to it, thereby creating an artificial DNA. Once ligated, these adapters are ***never removed***. The next claimed step leads to an even more unnatural result where some—but not all—of the adapter-bearing molecules are selectively amplified using "target specific" primers and the previously added universal primer. The result of this step is a mixture having unnaturally enriched copies of certain DNA sequences. These copies are enriched further in the next claimed step, and receive a new artificial addition—a sequencing tag. Finally, the enriched fraction of these artificial DNA copies is sequenced using a high-throughput approach. As such, the claims are not directed to the detection of the cell-free DNA itself or directed to a natural law or natural phenomenon.

35. The '220 patent claims are directed to specific, unconventional, non-routine methods for overcoming the previously unresolved problems in this area. For example, as of the date of the invention, it would not have been routine or conventional to amplify and use high-throughput sequencing to sequence nucleic acids obtained from circulating tumor DNA with the use of universal primers, molecular barcode and a sequencing tag in the context of the invention. The patent specification explains that sequencing was problematic after multiplex PCR because of artifacts such as primer-dimers formed during the amplification process, skilled artisans were therefore using methods such as microarrays instead of sequencing, and now that the patent teaches a way to minimize the formation of primer-dimer artifacts, multiplex PCR followed by sequencing could be done more effectively. '220 Patent, 47:36-55.

36. In allowing the '220 patent claims, the USPTO examiner found the claims to be non-routine and non-conventional, and stated:

> Claims 24-26 are free of the art. There are references that teach aspects of the method but would not render the claims obvious over these references because there is no motivation to modify a reference like Chowdary et al. (US PgPub 20080305473; December 2008) or Gocke et al (US Patent 6,156,504; December 2000) to include both multiplex using universal or common primers and a second step of nested amplification on the same multiplex amplified targets.

Ex. 2 (March 6, 2020 Non-final rejection), at 5.

37. None of the references (1) U.S. Patent App. Pub. No. 2010/0120038 ("Mir"), (2) Diego Spertini, *Screening of Transgenic Plants by Amplification of Unknown Genome DNA Flanking T-DNA*, 27 BioTechniques 308 (1999) ("Spertini"), (3) U.S. Patent App. No. 2007/0031857 ("Makarov"), (4) Wei-peng Wang et al., *Multiplex Single Nucleotide Polymorphism Genotyping By Adapter Ligation-Mediated Allele-Specific Amplification*, Analytical Biochemistry 355, 240–248 (2006) ("Wang"), or (5) Siebert et al., *An improved PCR method for walking in uncloned genomic DNA*, 23:6 Nucleic Acids Research 1087-88 (1995) ("Siebert"), either alone or in combination with each other, anticipate or render obvious any of the claims of the '220 patent.

GENOSITY'S INFRINGING ACTIVITIES

38. On information and belief, Genosity performs every step of claim 1 of the '220 patent when they use any of the Accused Products. Genosity's Myeloid NGS Molecular Profile uses "VariantPlex Myeloid Kit (ArcherDX Boulder, Co)." Ex. 3 (Myeloid NGS Molecular Profile –AA025a at https://gateway.igt.genosity.com/test-catalog/1275/1375-4); Ex. 4 (VariantPlexInfoSheetV3.pdf identified at https://gateway.igt.genosity.com/test-catalog/1275/1375-4). Genosity's website states that the AsTra testing system, including AsTra Profile, AsTra One, and AsTra Next, "utilize[e] the Archer ctDNA chemistry along with a set of

region specific primers designed by ArcherDx" and that "MRD status is generated by the ArcherDx MRD analysis Pipeline." Ex. 5 (Astra Profile – AA082 at https://gateway.igt.genosity.com/test-catalog/503702/503819); Ex. 6 (Astra One – AA080a at https://gateway.igt.genosity.com/test-catalog/503552/503652); Ex. 7 (Astra Next – AA081a at https://gateway.igt.genosity.com/test-catalog/503701/503826); Ex. 11 ("The Astra (Assessment and Tracking) system is a multistep testing platform . . . is used in subsequent MRD testing on ctDNA . . .")

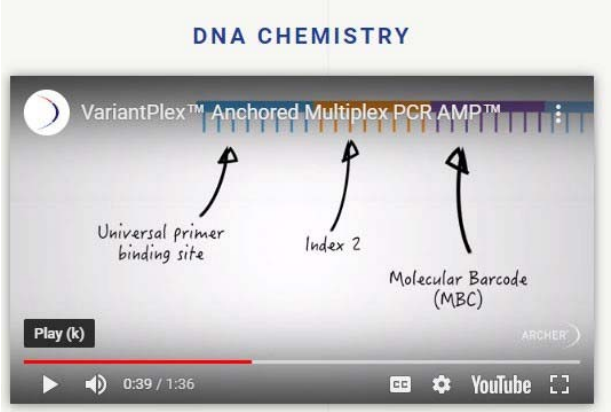
39. Genosity has obtained CLIA approval for its AsTra testing system. *See* Ex. 8 (https://www.businesswire.com/news/home/20200818005073/en/Genosity-Receives-CLIA-Approval-AsTra-Profile%E2%84%A2-AsTra). On information and belief, Genosity performs or causes to be performed every step of claim 1 of the '220 patent within its CLIA-approved process.

40. On information and belief, Genosity has performed the Myeloid NGS Molecular Profile test and the AsTra tests. *See e.g.*, Ex. 3 ("This test was performed at Genosity located at 485F US Route 1 South, Suite 110, Iselin, NJ 08830."); Exs. 5-7 ("This test was performed at the Genosity Laboratory located at 485F US Route 1 South, Suite 110, Iselin, NJ 08830.")

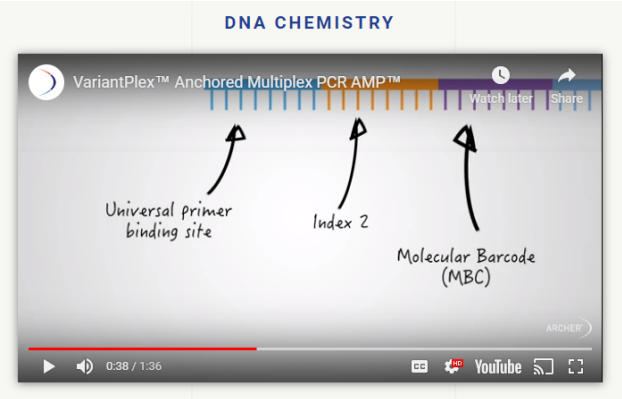
41. On information and belief, by using the Archer ctDNA chemistry, including in ArcherDX's VariantPlex Myeloid Kit used in Genosity's Myeloid NGS Molecular Profile test, Genosity ligates adaptors to cell-free DNA. The Archer ctDNA chemistry includes "**ligating an adapter molecule to the starting cDNA or DNA fragments** prior to PCR amplification." Ex. 9 (Technical Note, *The Use of Molecular Barcodes in Anchored Multiplex PCR*), at 1 (emphasis added).

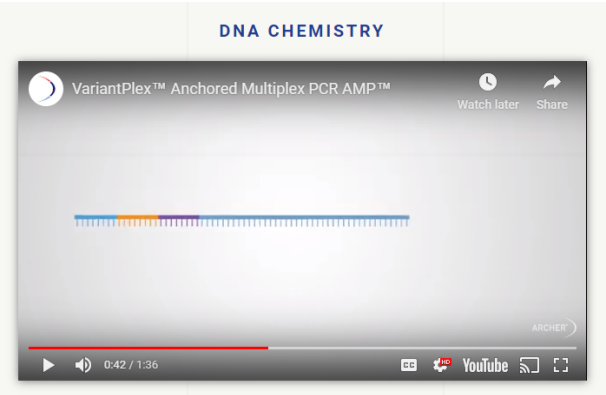
42. On information and belief, by using the Archer ctDNA chemistry, Genosity uses adaptors that include a universal priming sequence and a molecular barcode. The adaptors in the

Archer ctDNA chemistry include a "universal primer binding site" and a "molecular barcode (MBC)." *See* Ex. 10 (https://archerdx.com/technology-platform/technology/).



43. On information and belief, by using the Archer ctDNA chemistry, Genosity uses 1024 or more molecular barcodes. The Archer ctDNA chemistry utilizes a molecular barcode with 8 nucleotides. *See* Ex. 10 (https://archerdx.com/technology-platform/technology/).



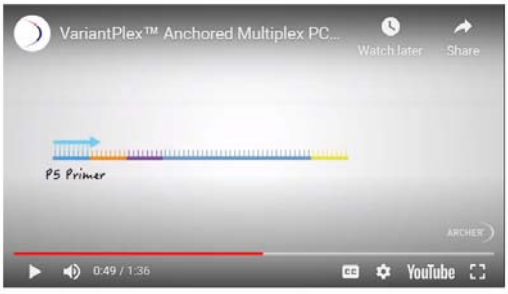


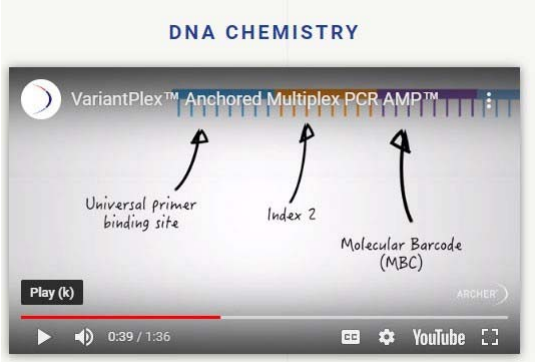
44. On information and belief, by using the Archer ctDNA chemistry, Genosity uses "a random 8-mer molecular barcode." *See* Ex. 9 (Technical Note, *The Use of Molecular Barcodes in Anchored Multiplex PCR*), at 1. The total number of different barcodes can be computed using 4^n, where n is the number of nucleotides. Given that the molecular barcode in the Archer ctDNA chemistry has 8 nucleotides, 65636 different barcodes are available.

45. On information and belief, by using the Archer ctDNA chemistry, Genosity then performs a PCR reaction. The Archer ctDNA chemistry includes "ligating an adapter molecule to

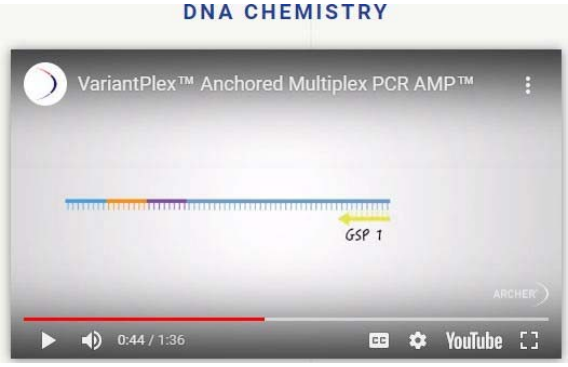
the starting cDNA or DNA fragments prior to **PCR amplification**." Ex. 9 (Technical Note, *The Use of Molecular Barcodes in Anchored Multiplex PCR*), at 1 (emphasis added).

46. On information and belief, by using the Archer ctDNA chemistry, Genosity performs the first PCR reaction using a universal primer. The Archer ctDNA chemistry uses a P5 primer and the P5 primer includes a "universal primer binding site." *See* Ex. 10 (https://archerdx.com/technology-platform/technology/).





47. On information and belief, by using the Archer ctDNA chemistry, Genosity a performs the first PCR reaction using at least 10 gene-specific primers (GSP1) to amplify at least 10 targets. The first PCR reaction in the Archer ctDNA chemistry "uses an anchored gene specific primer [GSP1] . . . ." *See* Ex. 10 (https://archerdx.com/technology-platform/technology/).



48. On information and belief, within the Archer ctDNA chemistry, "[f]or each target gene, 16 to 20 primer pairs (GSP1 and GSP2) are designed, covering the complete gene." Ex. 12 (Technical Note, *Archer Analysis Variant and CNV detection methods* (PN-MKT-0041 REV A)), at 2.

49. On information and belief, Genosity's Myeloid NGS Molecular Profile tests can detect up to 73 genes. Ex. 4 ("Genosity offers Myeloid NGS Panel that covers 73 genes")

50. On information and belief, AsTra Profile can test up to 19,407 genes. Ex. 5.

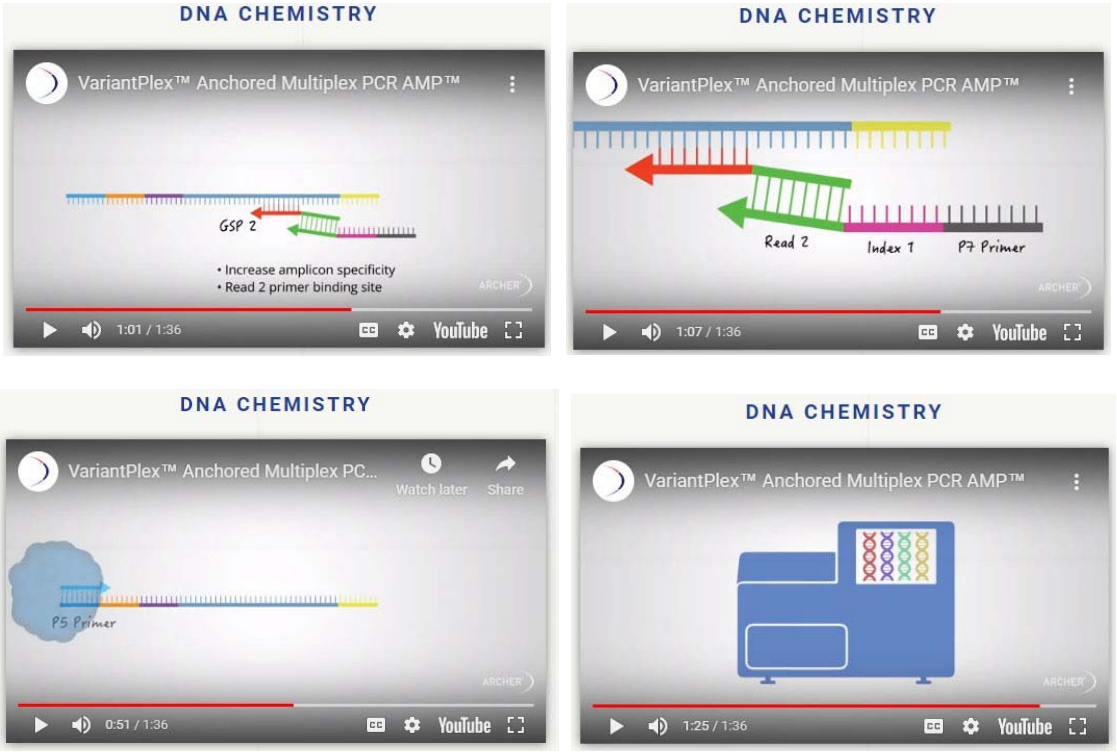
51. Thus, on information and belief, by using the Archer ctDNA chemistry, Genosity performs the first PCR to simultaneously amplify between 100 and 5,000 target loci using the first universal primer and between 100 and 5,000 target specific primers in a single reaction volume.

52. Thus, on information and belief, by using the Archer ctDNA chemistry, Genosity performs the first PCR to simultaneously amplify between 100 and 1,000 target loci using the first universal primer and between 100 and 1,000 target specific primers in a single reaction volume.

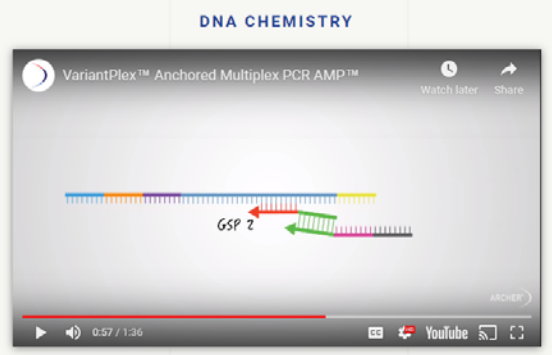
53. On information and belief, by using the Archer ctDNA chemistry, Genosity performs the processes of the AsTra testing system and Myeloid NGS Molecular Profile on cell-free DNA. Ex. 7 ("Preferred Sample Type Blood: 5-10 ml in Circulating Cell-Free DNA Tubes"); Ex. 11 ("The Astra (Assessment and Tracking) system is a multistep testing platform . . . is used in subsequent MRD testing on ctDNA . . .").

54. On information and belief, by using the Archer ctDNA chemistry, Genosity performs a second PCR step using at least 10 target specific primers (GSP2) and another universal primer. The Archer ctDNA chemistry utilizes the following reaction: "The second enrichment amplification uses a different nested gene specific primer to increase amplicon specificity and add a read 2 primer binding site. The second primer is a hybrid that contains a P7 primer and an Index

1 region for MiSeq." (Ex. 10 (*see* video "DNA Chemistry" at https://archerdx.com/technology-platform/technology/). The second primer amplifies against the same P5 primer in the adaptor (as shown in the annotated figure below) against which the gene-specific primer in the first PCR amplified. The P5 primer includes a "universal primer binding site." Ex. 10 (*see* video "DNA Chemistry" at https://archerdx.com/technology-platform/technology/).



55. On information and belief, in the Archer ctDNA chemistry, the second PCR step is a one-sided nested PCR. Specifically, "the second enrichment amplification uses a different nested gene specific primer," GSP2. Ex. 10 (*see* video "DNA Chemistry" at https://archerdx.com/technology-platform/technology/).



56. On information and belief, in the Archer ctDNA chemistry, "[f]or each target gene, 16 to 20 primer pairs (GSP1 and GSP2) are designed, covering the complete gene." Ex. 12 (Technical Note, *Archer™ Analysis Variant and CNV detection methods* (PN-MKT-0041 REV A)), at 2.

57. On information and belief, Genosity's Myeloid NGS Molecular Profile tests can detect up to 73 genes. Ex. 4 ("Genosity offers Myeloid NGS Panel that covers 73 genes").

58. On information and belief, AsTra Profile can test up to 19,407 genes. Ex. 5.

59. Thus, on information and belief, by using the Archer ctDNA chemistry, Genosity performs the second PCR to simultaneously amplify between 100 and 5,000 target loci using the second universal primer and between 100 and 5,000 target specific primers in a single reaction volume.

60. Thus, on information and belief, by using the Archer ctDNA chemistry, Genosity performs the second PCR to simultaneously amplify between 100 and 1,000 target loci using the second universal primer and between 100 and 1,000 target specific primers in a single reaction volume.

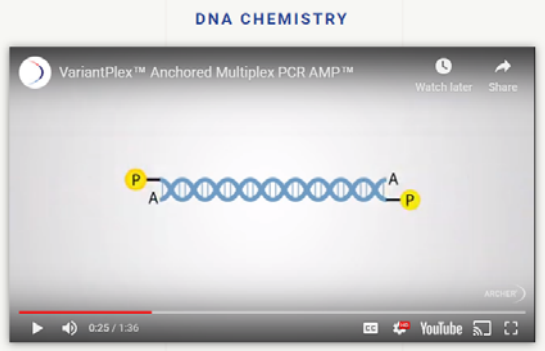
61. On information and belief, by using the Archer ctDNA chemistry, Genosity uses a primer with a sequence specific for high throughput sequencers. On information and belief, within the Archer ctDNA chemistry, "the second primer is a hybrid that contains a P7 primer and an Index

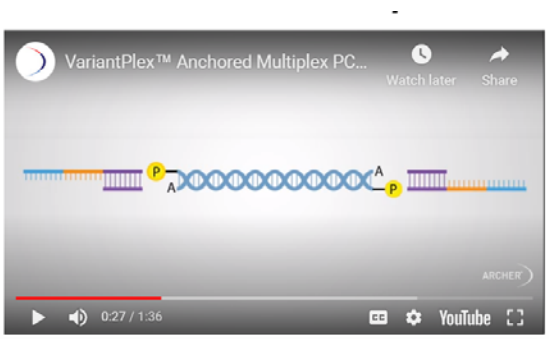
1 region for MiSeq." Ex. 10 (*see* video "DNA Chemistry" at https://archerdx.com/technology-platform/technology/).

62. On information and belief, by using the Archer ctDNA chemistry, Genosity performs high-throughput sequencing of the sequences amplified by the above steps. *See, e.g.*, Ex. 3 ("The library products are sequenced with 2 by 150 bp reads on either the Illumina MiSeq, NextSeq or NovaSeq sequencing instruments"); Ex. 5 ("The library products are sequenced with 2 by 150 bp reads on either the Illumina NextSeq or NovaSeq sequencing instruments").

63. On information and belief, by using the Archer ctDNA chemistry, Genosity performs the processes of the AsTra testing system using cell-free DNA derived from blood. *See, e.g.*, Ex. 7 ("Preferred Sample Type Blood: 5-10 ml in Circulating Cell-Free DNA Tubes"); Ex. 11 ("The Astra (Assessment and Tracking) system is a multistep testing platform . . . is used in subsequent MRD testing on ctDNA . . .").

64. On information and belief, by using the Archer ctDNA chemistry, Genosity performs the following steps: "[DNA] ends are blunted, a-tailed, and phosphorylated all in one reaction"; the "adaptor is then ligated." Ex. 10 (*see* video "DNA Chemistry" at https://archerdx.com/technology-platform/technology/).





COUNT I

(Infringement of U.S. Patent No. 10,731,220)

65. Natera repeats and realleges the foregoing paragraphs as if fully set forth herein.

66. Genosity has infringed and continues to infringe at least one claim of the '220 patent, pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by performing within the United States and without authority the tests of the Accused Products.

67. Genosity's infringement has damaged and will continue to damage Natera, which is entitled to recover the damages resulting from Genosity's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

68. Moreover, Genosity's infringement has caused, and will continue to cause, irreparable injury to Natera, for which damages are an inadequate remedy, unless Genosity is enjoined from any and all activities that would infringe the claims of the '220 patent.

PRAYER FOR RELIEF

WHEREFORE, Natera prays for a judgment in its favor and against Genosity and respectfully requests the following relief:

1. A judgment that Genosity directly infringes, induces infringement, and contributorily infringes the '220 patent.

2. An order enjoining Genosity and its officers, directors, agents, servants, affiliates, employees, divisions, branches, subsidiaries, parents, and all others acting in active concert therewith from further infringement of the '220 patent.

3. Damages or other monetary relief, including, but not limited to, costs and pre- and post-judgment interest, to Natera;

4. A determination that this is an exceptional case under 35 U.S.C. § 285 and an award of attorneys' fees and costs to Natera in this action;

5. Costs and expenses in this action;

6. An order awarding Natera any such other relief as the Court may deem just and proper under the circumstances.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Natera hereby demands a jury trial as to all issues so triable.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

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